Safety Evaluation of 'Watanabe Active Oyster Drink (Concentrate Type)' in Healthy Adults

Report from TTC Co., Ltd., Tokyo (participating in this clinical study as the Contact Research Organization)

Subjects and methods:

A clinical study was conducted to evaluate the safety of 4-week intake of 'Watanabe Active Oyster Drink (Concentrate Type)' that mainly consists of oyster extract concentrates in 24 healthy male and female adult subjects. They were randomly assigned to receive a regular dose of the test drink (12 subjects, 6 each of males and females; aged 36.3 ± 9.4 years) or a 3-fold increased dose of the test drink (12 subjects, 6 each of males and females; aged 39.7 ± 11.6 years) for 4 weeks. All subjects underwent routine examinations of anthropometrics (height, body weight, Body-Mass Index, blood pressures, and pulse rate), hematology and blood chemistry, and also urinalysis before the start and after the end of 4-week intervention, and at the end of 2-week follow-up. Safety was assessed on the basis of the incidence and severity of test drink-related adverse events self-reported throughout the intervention and follow-up periods, as well as of abnormal changes in anthropometric and laboratory test parameters.

Results and Conclusions:

None of subjects in both regular dose and 3-fold increased dose groups reported experiencing any adverse event during the intervention and follow-up periods. Anthropometric parameters or laboratory tests did not show any significant abnormalities in the 2 study groups at all the assessment timepoints. Although statistically significant mean changes from baseline in values of several laboratory tests were observed during the study period, all of these changes were limited within the reference interval or the normal range and judged by the Investigator not to be medically problematic.

Based on these results, it is concluded that 4-week intake of the test drink in doses up to 3-fold greater than the regular dose was safe in healthy male and female adults.

Tetsuro Yamamoto

Tetsuro Yamamoto Ph.D.
President/CEO

TTC Total Technological Consultant